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Cindy Baglietto  
Cindy Baglietto

**PATENT**

**Attorney Docket No. 22488-710**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application

Inventor(s): Jian -Yun Dong, et al.

Application No.: 09/600,521

Filed: November 5, 1999

Title Method of Treating Tumors Using Fas-Induced Apoptosis



**PATENT APPLICATION**

Art Unit: 1642

Examiner: Not Yet Assigned

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**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed below or on an attached Form PTO-1449 is information known to applicant(s). A copy of each listed publication and U.S. and foreign patent, except for pending U.S. applications, is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. If form PTO-1449 is enclosed, the Examiner is requested to initial and return it in accordance with MPEP §609.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56.

☒ This statement qualifies under 37 C.F.R. §1.97, subsection (b) because (check all that apply):

- ☐ (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  
-- OR --
- ☐ (2) It is being filed within 3 months of entry of a national stage  
-- OR --
- ☒ (3) It is being filed before the mail date of the first Office Action on the merits  
-- OR --
- ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.

☐ 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:

☐ a certification as specified in §1.97(e) is provided below; or

☐ a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☐ 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:

A. a certification as specified in §1.97(e) is completed below; and

B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**

C. a fee of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☒ **Fee Authorization.** The Commissioner is hereby authorized to charge the above-referenced fees of \$0 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.22488-710).

Respectfully submitted,


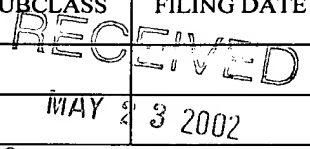
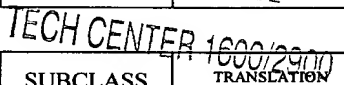
WILSON SONSINI GOODRICH & ROSATI

Dated: May 16, 2002

By: 

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| <b>INFORMATION DISCLOSURE CITATION</b><br><br><b>PTO-1449</b> MAY 20 2002<br> |                                                                                                                                                                                                                                                                                                                              | ATTY. DOCKET NO.<br>22488-710 | SERIAL NO.<br>09/600,521 |       |                                                                                     |                                                                                     |                          |
|                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                              | APPLICANT Jian-Yun Dong       |                          |       |                                                                                     |                                                                                     |                          |
|                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                              | FILING DATE 11/5/1999         | GROUP 1642               |       |                                                                                     |                                                                                     |                          |
| <b>U.S. PATENT DOCUMENTS</b>                                                                                                                                   |                                                                                                                                                                                                                                                                                                                              |                               |                          |       |                                                                                     |                                                                                     |                          |
| EXAMINER'S INITIALS                                                                                                                                            | PATENT NO.                                                                                                                                                                                                                                                                                                                   | DATE                          | NAME                     | CLASS | SUBCLASS                                                                            | FILING DATE                                                                         |                          |
|                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                              |                               |                          |       |                                                                                     |  |                          |
| <b>FOREIGN PATENT DOCUMENTS</b>                                                                                                                                |                                                                                                                                                                                                                                                                                                                              |                               |                          |       |  |                                                                                     |                          |
| EXAMINER'S INITIALS                                                                                                                                            | PATENT NO.                                                                                                                                                                                                                                                                                                                   | DATE                          | COUNTRY                  | CLASS | SUBCLASS                                                                            | TRANSLATION                                                                         |                          |
|                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                              |                               |                          |       |                                                                                     | YES                                                                                 | NO                       |
|                                                                                                                                                                | WO 97/33617                                                                                                                                                                                                                                                                                                                  | 18/9/1997                     | PCT                      | A61K  | 39/395                                                                              | <input type="checkbox"/>                                                            | <input type="checkbox"/> |
|                                                                                                                                                                | WO 98/37185                                                                                                                                                                                                                                                                                                                  | 27/8/1998                     | PCT                      | C12N  | 15/00                                                                               | <input type="checkbox"/>                                                            | <input type="checkbox"/> |
|                                                                                                                                                                | 0675200 A1                                                                                                                                                                                                                                                                                                                   | 04/10/1995                    | EPO                      | C12N  | 15/19                                                                               | <input type="checkbox"/>                                                            | <input type="checkbox"/> |
|                                                                                                                                                                | WO 01/79495                                                                                                                                                                                                                                                                                                                  | 25/10/2001                    | PCT                      | C12N  | 15/12                                                                               | <input type="checkbox"/>                                                            | <input type="checkbox"/> |
|                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                              |                               |                          |       |                                                                                     | <input type="checkbox"/>                                                            | <input type="checkbox"/> |
| <b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>                                                                                  |                                                                                                                                                                                                                                                                                                                              |                               |                          |       |                                                                                     |                                                                                     |                          |
|                                                                                                                                                                | Hiroshi Arai; "Gene Transfer of Fas Ligand Induces Tumor Regression <i>in vivo</i> "; December 1997; Prac. Natl. Acad. Science USA; Vol. 94; pp. 13862-13867.                                                                                                                                                                |                               |                          |       |                                                                                     |                                                                                     |                          |
|                                                                                                                                                                | Margot Shiner; "Are Intraepithelial Lymphocytes in Celiac Mucosa Responsible for Inducing Programmed Cell Death (Apoptosis) in Enterocytes? Histochemical Demonstration of Perforins in Cytoplasmic Granules in Intraepithelial Lymphocytes"; October 1998; Journal of Pediatric Gastroenterology and Nutrition; pp. 393-396 |                               |                          |       |                                                                                     |                                                                                     |                          |
|                                                                                                                                                                | Ronald P. Leon; "Adenoviral-Mediated Gene Transfer in Lymphocytes"; October 1998; Proc. Natl. Acad. Sci. USA; Vol. 95, pp. 13159-13164.                                                                                                                                                                                      |                               |                          |       |                                                                                     |                                                                                     |                          |
|                                                                                                                                                                | GN Barber; "Host Defense, Viruses and Apoptosis"; 2001; Cell Death and Differentiation; pp. 113-126.                                                                                                                                                                                                                         |                               |                          |       |                                                                                     |                                                                                     |                          |
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|                                                                                                                                                                | Shunsuke Kagawa; "Antitumor Activity and Bystander Effects of the Tumor Necrosis Factor-Related Apoptosis-Inducing Ligand (TRAIL) Gene; April 15, 2001; Cancer Research 6; pp. 3330-3338.                                                                                                                                    |                               |                          |       |                                                                                     |                                                                                     |                          |
|                                                                                                                                                                | Shi-Qiong Xu "P21 <sup>WAF1/CIP1</sup> Inhibits Initiator Caspase Cleavage by TRAIL Death Receptor DR4"; 2000; Biochemical and Biophysical Research Communications 269; pp. 179-190.                                                                                                                                         |                               |                          |       |                                                                                     |                                                                                     |                          |
|                                                                                                                                                                | Thomas S. Griffith; "Adenoviral-Mediated Transfer of the TNF-Related Apoptosis-Inducing Ligand-Apo-2 Ligand Gene Induces Tumor Cell Apoptosis; 2000; The American Association of Immunologists; pp. 2886-2894.                                                                                                               |                               |                          |       |                                                                                     |                                                                                     |                          |
|                                                                                                                                                                | T.S. Griffith, et al., "Adenoviral-mediated gene transfer of TRAIL induces tumor cell apoptosis", April 2000, Vol 14, No. 6, p. A1003 (abstract).                                                                                                                                                                            |                               |                          |       |                                                                                     |                                                                                     |                          |
| EXAMINER                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                              |                               | DATE CONSIDERED          |       |                                                                                     |                                                                                     |                          |

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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| <b>INFORMATION DISCLOSURE CITATION</b><br>PTO-1449 MAY 20 2002<br>U.S. PATENT & TRADEMARK OFFICE                                                                                                                                                                                                                     |            | ATTY. DOCKET NO.<br>22488-710 |                 | SERIAL NO.<br>09/600,521 |          |                                                          |
|                                                                                                                                                                                                                                                                                                                      |            | APPLICANT Jian-Yun Dong       |                 |                          |          |                                                          |
|                                                                                                                                                                                                                                                                                                                      |            | FILING DATE 11/5/1999         |                 | GROUP 1642               |          |                                                          |
| <b>U.S. PATENT DOCUMENTS</b>                                                                                                                                                                                                                                                                                         |            |                               |                 |                          |          |                                                          |
| EXAMINER'S INITIALS                                                                                                                                                                                                                                                                                                  | PATENT NO. | DATE                          | NAME            | CLASS                    | SUBCLASS | FILING DATE                                              |
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| <b>FOREIGN PATENT DOCUMENTS</b>                                                                                                                                                                                                                                                                                      |            |                               |                 |                          |          |                                                          |
| EXAMINER'S INITIALS                                                                                                                                                                                                                                                                                                  | PATENT NO. | DATE                          | COUNTRY         | CLASS                    | SUBCLASS | TRANSLATION                                              |
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| <b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>                                                                                                                                                                                                                                        |            |                               |                 |                          |          |                                                          |
| X. Wei, "Killing effect of TNF-related apoptosis including ligand regulated by tetracycline on gastric cancer cell line NCI-N87", Database EMBASE online – Elsevier Science Publishers and World Journal of Gastroenterology, 2001 7/4, pp. 559-562 (abstract)                                                       |            |                               |                 |                          |          |                                                          |
| Adrian E. Morelli, et al., "Neuronal and glial cell type-specific promoters within adenovirus recombinants restrict the expression of the apoptosis-inducing molecule Fas ligand to predetermined brain cell types, and abolish peripheral liver toxicity", 1999, Journal of General Virology, Vol. 80, pp. 571-583. |            |                               |                 |                          |          |                                                          |
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| T. Gura, "How TRAIL Kills Cancer Cells But Not Normal Cells", 1977, Cancer Research, Vol. 77, p. 768.                                                                                                                                                                                                                |            |                               |                 |                          |          |                                                          |
| W. Roth, et al. Todesliganden/Todesrezeptoren als Angriffspunkt der somatischen Genterapie Maligner Gliome; March 1999; Neuroforum, Vol. 5, No. 3; pp. 87-92. Abstract written in English on p. 87.                                                                                                                  |            |                               |                 |                          |          |                                                          |
| Tammy E. Hedlund, et al., "Adenovirus-mediated expression of Fas ligand induces apoptosis of human prostate cancer cells", February 1999, Database BIOSIS online – Biosciences Information Service and Cell Death and Differentiation, February 1999, Vol. 6, No. 2, pp. 175-182 (abstract).                         |            |                               |                 |                          |          |                                                          |
| Magdalene K. Sgagias, et al., "Induction of apoptosis by adenovirus-mediated over-expression of BRCA1 in T47D human breast cancer cells", March 2000, Proceedings of the American Association for Cancer Research Annual, No. 41, p. 537.                                                                            |            |                               |                 |                          |          |                                                          |
| EXAMINER                                                                                                                                                                                                                                                                                                             |            |                               | DATE CONSIDERED |                          |          |                                                          |

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| <b>FOREIGN PATENT DOCUMENTS</b>                                                                                                                                                                                                                                                                            |            |                               |         |                          |          |                          |                          |
| EXAMINER'S INITIALS                                                                                                                                                                                                                                                                                        | PATENT NO. | DATE                          | COUNTRY | CLASS                    | SUBCLASS | TRANSLATION              |                          |
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| <b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>                                                                                                                                                                                                                              |            |                               |         |                          |          |                          |                          |
| A.T. Larregina, et al., "FasL induces Fas/Apol-mediated apoptosis in human embryonic kidney 293 cells routinely used to generate E1-deleted adenoviral vectors", April 1998, Database BIOSIS online – Biosciences Information Service and April 1998, Gene Therapy, Vol. 5, No. 4, pp. 563-568 (abstract). |            |                               |         |                          |          |                          |                          |
| Zhang, Huang-Ge, et al.; "Application of a Fas Ligand Encoding a Recombinant Adenovirus Vector for Prolongation of Transgene Expression; March 1998, Journal of Virology, Vol. 72, No. 3; pp. 2483-2490.                                                                                                   |            |                               |         |                          |          |                          |                          |
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| EXAMINER                                                                                                                                                                                                                                                                                                   |            |                               |         | DATE CONSIDERED          |          |                          |                          |

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